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Mark E. Samuels

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

04/29/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                       |  |
|------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/552,158  | <b>Applicant(s)</b><br>SAMUELS ET AL. |  |
|                              | <b>Examiner</b><br>MARYAM MONSHIPOURI | <b>Art Unit</b><br>1656               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 1-92, 98-117 and 123-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 93-97 and 118-122 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/25/07& 6/29/07 & 8/24/09 & 8/24/09 & 9/24/09 &10/15/09.

Applicant's response to restriction of 1/29/2010 is acknowledged. Applicant elected Group II(B) claims 92-97 and 118-122 and SEQ ID NO:12 without traverse. Claims 1-91, 98-117 and 123-127 are withdrawn as drawn to non-elected invention. Upon review of the previous office action it became apparent that claim 92, which is a product claim should not have been included into Group II method Claims. Therefore, claim 92 is hereby withdrawn. The examiner regrets said inadvertent error.

On 4/6/2010 the examiner called up Mr. Alan Grant to discuss merits of the invention. During the course of interview it was decided to rejoin SEQ ID NO:10 and 11 with the elected invention.

#### **DETAILED ACTION**

Claims 93-97, 118-127 and SEQ ID NO:10-12 are under examination on the merits.

#### ***Claim Objections***

Claims 93-97 and 118-122 are objected to because of the following informalities: Claim 93 depends from non-elected claims. Applicant is advised to write said claim independently in response to this office action. Claims 94-97 and 118-122 are added merely for depending on base claim 93 under objection. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-97 and 118-122 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of use of polypeptides comprising an amino acid sequence having at least 90% identity to SEQ ID NO:10-12 in their entireties for treating the disease of iron metabolism, it does not reasonably provide enablement for a method of use of fragments of said polypeptides comprising at least 10 amino acid residues.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which residues within the 200, 313 and 426 residues of SEQ ID NO:10-12, respectively, need to be retained within the claimed fragments in order to modulate hemojuvelin and thereby treat the diseases of iron metabolism. Such fragments leave (200-10=) 119, (313-10=) 303 and (426-10=) 416 residues of each of SEQ ID NO:10-12, respectively subject to guess work and speculation. In addition, no examples of such small fragments are provided either. The prior art is unpredictable as to which residues within a fragment of at least ten amino acid residues are in charge of assigning hemojuvelin modulation function.

Therefore due to lack of sufficient guidance and examples provided and due to unpredictability of prior art as to which residues within the claimed fragments are in

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charge of hemojuvelin modulation and thereby treating the disease of iron metabolism one of ordinary skill has to go through the burden of undue experimentation in order to practice the invention and as such the claims go beyond the scope of the disclosure.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 93, 96-97 and 118-122 are rejected under 35 U.S.C. 102(a) as being anticipated by Tang et al. “Tang” (WO 03/046152, June 2003) . Tang teaches a polypeptide namely its SEQ ID NO:44, that displays 100% identity to SEQ ID NO:11 of this invention (see instant SEQ ID NO:11 Geneseq Database search results , hit #2, under PAIR). In page 48, line 29, Tang teaches that its polypeptides or fragments thereof may be administered to a subject for treating autoimmune hemolytic anemia, which inherently is a disease related to iron metabolism. Such polypeptide compositions of Tang when administered to a subject may inherently inhibit hepcidin or hemojuvelin activity and inherently modulate iron transport across cell membranes, anticipating claims 93, 96-97 and 118-122 of this invention.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 93-97 and 118-122 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6 of U.S. Patent No. 7,511,018. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of treating the disease of iron metabolism utilizing a polypeptide comprising SEQ ID NO:15 (see patent claims)

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inherently embraces the methods of this invention which utilize polypeptides comprising SEQ ID NO:10-12.

**No claim is allowed.**

***Allowable Subject Matter***

Methods of administering SEQ ID NO:10 and 12 or 90% or more homologs thereof for treatment of a patient with a disease related to iron metabolism is free of prior art. Further, the prior art fails to suggest such specifically claimed methods. Hence, said methods are also non-obvious.

**Note:** U.S. patent No. 7,534,764 (currently withdrawn) may be of interest to applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARYAM MONSHIPOURI whose telephone number is (571)272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rao Munjunath can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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